

1 The United States remains a real party in interest in this matter, even though it has not  
intervened in the action. *United States Dept. of Transp. ex rel. Arnold v. CMC Engineering*, 564  
F.3d 673, 675 (3d Cir. 2009); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360  
F.3d 220, 231 (1st Cir. 2004). The False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, is the

(FCA) violation predicated on a violation of the Anti-Kickback Statute (AKS). A plaintiff in a FCA case predicated on a violation of the AKS need not allege or prove that remuneration in the form of a discount was inconsistent with fair market value or commercially unreasonable. Nor does the provision of accurate information about the benefits of an arrangement insulate an entity from being held liable for conduct that violates the AKS.

The United States takes no position on whether the relator has adequately pleaded facts that would state a cognizable claim under the FCA as properly interpreted. The United States also takes no position on whether the relator has sufficiently pleaded elements of falsity, causation, scienter, or materiality. The United States submits this brief exclusively to clarify what the FCA and the AKS require as to these issues. If the Court finds that the relator's Complaint does not satisfy Federal Rule of Civil Procedure ("Rule") 9(b), the Court need not reach defendants' other arguments or any of the issues addressed in this Statement of Interest. In that case, the United States respectfully requests that the Court dismiss the case without prejudice to the United States. If the Court finds that the relator's Complaint satisfies Rule 9(b), and therefore addresses the issues discussed herein, the United States respectfully urges the Court to reject defendants' arguments for the reasons set forth below.

## **ARGUMENT**

1. In its Motion, Novartis asserts that to state a FCA claim predicated on a violation of the AKS, a plaintiff must allege that the remuneration offered or paid to induce federal health care program referrals was commercially unreasonable or inconsistent with fair market value.

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United States government's primary tool to redress fraud on the government. Thus, the United States has a keen interest in the development of the law in this area and in the correct application of the law in this, and similar, cases. Accordingly, courts routinely accept Statements of Interest filed by the United States in FCA cases such as this one. *See, e.g., United States v. Johnson & Johnson*, Civ. A. No. 12-7758, 2017 WL 2367050, at \*1 (D.N.J. May 31, 2017); *Druding v. Care Alternatives, Inc.*, 164 F. Supp. 3d 621, 626 (D.N.J. 2016).

Doc. 24-1 at 13 (“Relator has not adequately alleged that the discounts provided by Novartis were unreasonable, which is a prerequisite to establishing illegal remuneration [under the AKS].”). Novartis has misstated the law. There may be some cases in which commercially reasonable or fair market value remuneration does not constitute an illegal kickback under the AKS. And a defendant might use evidence of fair market value or commercial reasonableness to argue that it lacked an intent to induce referrals. However, as a matter of law, the AKS does not *require* that remuneration in the form of a discount be commercially unreasonable or inconsistent with fair market value. As explained below, Novartis’s argument is inconsistent with the plain and broad language of the statute and is contradicted by case law in the Third Circuit.

The AKS prohibits “knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly ... in return for purchasing [or] ordering ... any ... item for which payment may be made ... under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(1)(B). The AKS also prohibits “knowingly and willfully offer[ing] or pay[ing] remuneration (including any kickback, bribe, or rebate) directly or indirectly ... to any person to induce such person ... to purchase ... [or] order ... any item for which payment may be made ... under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2)(B). Nowhere does the statute reference — explicitly or implicitly — an additional element of fair market value or commercial unreasonableness. Indeed, the Third Circuit held that the term “remuneration” should be construed broadly to mean “not only sums for which no actual service was performed but also those amounts for which some professional time was expended.” *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985). Accordingly, courts, including within the Third Circuit, have construed the term “remuneration” to mean “anything of value — and in any form — which is given in return for, or to induce, a referral for federal

healthcare services....” *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 677 (W.D. Pa. 2014). *See also United States v. Health Alliance of Greater Cincinnati*, No. 1:03-CV-00167, 2008 WL 5282139, at \*7 (S.D. Ohio Dec. 18, 2008). Courts have also stated clearly that discounts are a form of remuneration under the AKS. *United States v. Shaw*, 106 F. Supp. 2d 103, 113 (D. Mass. 2000) (stating that a “discount” is a “subset” of remuneration).<sup>2</sup>

Consistent with the plain language of the AKS, courts within the Third Circuit have already rejected Defendant Novartis’s invitation to the Court to graft a fair market value/commercial unreasonableness element onto the statute.

In the Third Circuit, remuneration is illegal under the AKS if one purpose of the remuneration was to induce referrals, regardless of whether the remuneration may have also had a legitimate purpose, such as paying fair market value for services. *Greber*, 760 F.2d at 72 (holding that as long as one purpose of remuneration was to induce patient referrals the AKS was violated). As explained in *Cooper v. Pottstown Hosp.*, “[b]ecause the structure of a proscribed exchange may vary, the [AKS], at its core, ‘is aimed at the inducement factor.’” No. 13-01137, 2015 WL 1137664, at \*3 (E.D. Pa. Mar. 13, 2015) (citing *Greber*, 760 F.2d at 71); *see also Ashcroft*, 39 F. Supp. 3d at 678 (“the crux of whether the [AKS] ... [is] violated” is whether the defendant “had the requisite intent to violate the statute,” namely, “whether the parties entered business arrangements in exchange for, or to induce, patient referrals”).

In *Ashcroft*, the court made clear that as long as remuneration is intended to induce referrals, it is unlawful — even where the remuneration is fair market value or commercially

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<sup>2</sup> The AKS does expressly exclude certain discounts from the definition of remuneration, namely, “a discount ... in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(3)(A). Defendants do not contend that the rebates at issue here fit within this statutory exception.

reasonable. *Id.* at 677. Again, as courts have noted, this is because “[t]he reason behind the transaction and the requisite state of mind underlying the criminal act are more significant than form and label.” *Shaw*, 106 F. Supp. 2d at 116. Thus, in order to establish a violation of the AKS, it is sufficient that the plaintiff allege that the defendant (1) knowingly and willfully (2) offered, paid, solicited or received remuneration (3) intended to induce patient referrals. *United States v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at \*4 (E.D. Pa. June 19, 2017) (citing *Ashcroft*, 39 F. Supp. 3d at 676). Nothing more is required.

Novartis’ contrary position is based on two out-of-circuit district court cases, one in the Western District of Washington and one in the Northern District of Illinois. Doc. 24 at 11 (citing *United States v. Ctr. For Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213 (W.D. Wash. 2011) and *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622 (N.D. Ill. 2006)). For the reasons explained, however, the conclusions of these two courts are inconsistent with the plain language of the AKS and with case law within the Third Circuit.

Moreover, these decisions ignore that an illegal inducement can exist even where a transaction could qualify as being fair market value or commercially reasonable. Take, for example, the situation in which a hospital selects one physician over another to serve as a Medical Director not because the former is more qualified but rather because he agrees to increase his referrals if he is selected for the job. In this circumstance, the preference in awarding the Medical Director position is clearly being used to induce referrals even if the hospital pays a fair market value/commercially reasonable fee to the new Medical Director. And, as a result, the transaction would still give rise to concerns about the physician gaining an unfair competitive advantage by trading on referrals and making unnecessary and excessive

referrals to retain his position at the hospital. This goes to the very heart of what the AKS was designed to prevent.

2. In its Motion, Novartis also states that providing accurate information about the way the Medicare Part D Plan functions does not itself amount to illegal remuneration. Doc. 24 at 14 (“But Relator does not allege — nor could he — that this information was inaccurate; in fact, he admits that it correctly reflected the way in which Medicare Part D covered Gilenya.”). Novartis goes on to argue that because its marketing of Gilenya to ESI was truthful, Novartis’s offer of a Medicare Part D discount could not, as a matter of law, be actionable under the AKS. *Id.* (“The mere provision of this truthful information about Medicare Part D risk sharing could not have constituted an illegal offer of remuneration.”). As explained below, Novartis’s argument has no merit.

As a threshold matter, the relator alleges that the illegal remuneration offered and paid by Novartis to ESI was the Medicare Part D discount for Gilenya, not Novartis’s explanation of the financial benefits of that discount to ESI. *See* Compl. ¶ 105. Accordingly, that the relator arguably failed to allege that Novartis’s explanation to ESI of the financial benefits of accepting that discount was inaccurate is wholly beside the point.

In addition, neither of the cases relied upon by Novartis even addresses, much less supports, the claim that the veracity of statements made with an offer of a kickback can insulate a defendant from AKS liability. *See* Doc. 24 at 14. The issue in *United States v. Miles* was whether the activities of a marketing firm, which received fees from a home health agency based on the number of Medicare patients secured for the agency, could constitute a referral under the AKS. 360 F.3d 472, 480 (5th Cir. 2004) (stating “[t]he only issue in dispute is whether Premier’s [*i.e.*, the marketing firm] activities constituted referrals within the meaning of the

[AKS]”). The *Miles* opinion neither analyzes the element of remuneration nor touches upon the veracity of Premier’s marketing materials. *Id.* The other case relied upon by Novartis, *United States v. Medtronic*, 189 F. Supp. 3d 259 (D. Mass. 2016), is similarly inapposite. At issue in *Medtronic* was whether the defendant company’s guidance to physicians “on billing Medicare for procedures that Medtronic provided for free” constituted illegal remuneration. *Id.* at 270. The court held that it did. *Id.* The veracity of that guidance itself was not considered or discussed by the court. *Id.* at 270–71.

It is not surprising that there is no support for Novartis’s proposition. That is because the AKS imposes liability for conduct, not speech. And the Supreme Court has held on several occasions that the First Amendment does not protect speech — even truthful speech — that is “used as an integral part of conduct in violation of a valid criminal statute.” *United States v. Stevens*, 559 U.S. 460, 471 (2010) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 498 (1949)); see also *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557, 563–64 (1980) and *Wisconsin v. Mitchell*, 508 U.S. 476, 488–89 (1993) (“The First Amendment ... does not prohibit the evidentiary use of speech to establish the elements of a crime”). In other words, a truthful offer of a kickback is still a kickback. If a hospital offers to pay a physician for his referrals, and in so doing makes truthful statements about the financial benefits to both parties about the arrangement, the truthfulness of those statements does not render the arrangement legal or otherwise insulate the parties from liability under the AKS or FCA.

## CONCLUSION

As noted above, the United States take no position on the Defendants' motions pursuant to Rule 9(b). If the Court reaches the remaining arguments in the motions to dismiss, the United States respectfully requests that the Court considers its views as to the issues herein.

DATED: September 18, 2018

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I, Andrew A. Caffrey, III, hereby certify that on September 18, 2018, I caused a copy of the forgoing document, The United States Of America's Statement Of Interest In Response To Defendant Novartis Pharmaceuticals Corporation's Motion To Dismiss (Doc. 24), to be served on all registered counsel of record via ECF.

Dated: September 18, 2018  
Newark, New Jersey

s/ Andrew A. Caffrey, III  
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